

REMARKS

This Amendment is made in response to the Official Action mailed January 11, 2008. A request for a two-month extension of time accompanies this Amendment. Claims 7 and 8 have been cancelled. Claims 1 and 6 have been amended. New claims 9 and 10 have been added. Accordingly, claims 1-6, 9 and 10 are now pending in this application. Reconsideration and withdrawal of the objections to and rejections of this application are respectfully requested in view of the above amendments, and further, in view of the following remarks.

Preliminarily, Applicants claim 1 has been amended to clarify that the film-forming component of the instant anhydrous liquid tooth whitening composition has a weight range between 5 and 30% w/w. Support for this amendment can be found on page 7, lines 1-2, of the instant specification. Claim 6 has been amended in order to clarify that ethanol is the solvent for the film forming agent. Support for this amendment can be found on page 7, lines 4-9, of the instant specification. New claim 9 has been added and merely reorganizes the steps of the method as originally claimed in cancelled claim 8. Further, new claim 10 has been added and is directed to a composition of claim 1, wherein the water-insoluble film-forming agent is a microcrystalline cellulose, a poly(urethane) or a poly(acrylamide). Support for new claim 10 can be found on page 6, lines 28-29, of the instant specification.

Claims 1-6 have been rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application publication number US 2004/0086468 (now U.S. Patent 6,893,629), published May 6, 2004, to Prorise et al. ("Prorise"). In particular, the Action asserts that Prorise teaches a tooth whitening delivery system comprising a PVP-hydrogen peroxide complex, glycerol, hydroxypropylmethyl cellulose, ethyl cellulose and ethanol. Reconsideration and withdrawal of the rejection are respectfully requested.

Applicants submit that the amount of film forming component present in Prorise does not fall within the scope of the present claims. Amended independent claim 1 contains 5 to 30% w/w of the film forming component, wherein the film forming component is a water-insoluble film forming agent and a solvent thereof.

Looking specifically at Example 1 of Prorise, it is important to note that of the two film forming agents disclosed only the ethyl cellulose material is water-insoluble. See, page 198 of the Handbook of Pharmaceutical Excipients, Third Ed. (2000), included herewith. Hydroxypropylmethyl cellulose, despite being a cellulose material is not water-insoluble, indeed, it is soluble in cold water. See, page 253 of the Handbook of Pharmaceutical Excipients, Third Ed. (2000), included herewith. Furthermore, in Example 1, 2.8 g of a water-insoluble film forming agent (ethyl cellulose) is solubilized in 100 ml of absolute ethanol which equates to 3.54% w/w (using the specific gravity of ethanol of 0.79 g). This is

clearly outside the 5 to 30% w/w range of the film forming component claim 1 of the present invention.

Example 2 of Prosize uses 2.0 g of a water-insoluble film forming agent (ethyl cellulose) in 100 ml of absolute ethanol which equates to 2.53% w/w. Again, the teaching is outside the 5 to 30% w/w range of film forming component of present claim 1. Example 3 of Prosize uses 7.0 g of a water-insoluble film forming agent (ethyl cellulose) in 200 g of absolute ethanol. This is equivalent of 3.5% w/w and also falls outside the 5 to 30% w/w range of present claim 1. Accordingly, Prosize does not teach or suggest the tooth whitening films of the present invention.

Since Prosize does not teach or suggest each and every element of claims 1-6, the claims cannot be said to be anticipated by Prosize. Therefore, reconsideration and withdrawal of the rejection of claims 1-6 under §102(e) are requested.

Claims 7 and 8 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Prosize in view of U.S. Patent No. 6,517,350, granted February 11, 2003, to Diasti et al. ("Diasti"). In particular, the Examiner asserts that Diasti teaches a tooth whitening compound with a carrier selected for adhering to the person's teeth; and that the composition can be applied to the teeth by methods including painting or coating. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 7 and 8 have been canceled. New claim 9 has been added and is directed to a method of whitening the teeth with a composition of claim 1 by (a) preparing a tooth whitening composition according to claim 1; (b) painting the composition onto teeth to be whitened; (c) maintaining the composition in contact with the teeth for a plurality of hours per day; and then repeating steps (b) and (c) for multiple days to thereby whiten the teeth. As discussed above, the composition of claim 1 is not anticipated or obvious over Prosize. Diasti relates to a composition for whitening teeth comprising a resin or varnish for adhering the composition to the teeth. There is no teaching of a water-insoluble film forming agent, let alone from 5 to 30% w/w of a film-forming component consisting essentially of a water-insoluble film-forming agent and a solvent for the film-forming agent. Again, the hydroxy propyl cellulose taught in the examples, while a cellulose material, is water soluble. See, page 245 of the Handbook of Pharmaceutical Excipients, Third Ed. (2000), included herewith.

Therefore, one of skill in the art reading Prosize alone, or in any fair combination with Disasti, would not have been motivated to modify the teaching in Prosize to arrive at the instant invention. A *prima facie* case of obviousness has not been established. Favorable reconsideration and withdrawal of the rejection under Section 103(a) are requested.

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In view of the above remarks, favorable reconsideration of claims 1-6, favorable consideration of new claims 9 and 10 and allowance of this application with claims 1-6, 9 and 10 are earnestly solicited.

Respectfully submitted,

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